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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,037	11/14/2006	Fraser James Buchanan	36290-0425-00-US (229895)	4052

23973 7590 10/28/2010

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EXAMINER	
SCOTT, ANGELA C	
ART UNIT	PAPER NUMBER
1767	

NOTIFICATION DATE	DELIVERY MODE
10/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
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Office Action Summary	Application No.	Applicant(s)	
	10/589,037	BUCHANAN, FRASER JAMES	
	Examiner	Art Unit	
	Angela C. Scott	1767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19-22,24,27-34,36 and 39-48* is/are pending in the application.

4a) Of the above claim(s) *1,19-21,30-33 and 42-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,24,27-29,34,36 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of July 30, 2010 has been fully considered. Claims 22 and 34 have been amended. Claims 1, 19-22, 24, 27-34, 36 and 39-48 are pending with claims 1, 19-21, 30-33 and 42-48 withdrawn from consideration. The office action mailed on May 17, 2010 is indeed a non-final rejection.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22, 24, and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby (US 2004/0133237).

Regarding claims 22 and 29, Shalaby teaches an absorbable medical device, such as a suture, having controlled physical properties, that is irradiated with radiation from an electron beam (¶4, 6). A suture has a core and an outer surface by definition. It is the outer surface that is irradiated with the radiation because the irradiation occurs after the article has formed (¶6). These sutures are sterilized, so therefore, the entire outer surface is irradiated (¶6). Shalaby also teaches that the controlled physical property can be controlled mass loss of the suture, i.e., controlled degradation of the suture through molecular weight loss. Moreover, Shalaby teaches that the it is the irradiation which changes the physical properties and the physical properties vary inversely with the radiation dose (¶5). In other words, the more radiation something receives, such as the outer surface of the suture, the less its physical property, i.e., molecular weight. Therefore, since the outer surface receives more of the radiation, it would have a lower molecular weight than the inner core of the suture. This difference in molecular weight is by definition a gradient (changes gradually). Finally, the rate of bioabsorbability, i.e., degradation, is dependent upon the molecular weight of the component. Therefore, since the outer surface has a lower molecular weight, it would have a greater rate of bioabsorbability.

Regarding claim 24, The rate of bioabsorbability (degradation) the suture (implant) is determined by the type of polymer and the amount of radiation it receives. Therefore, one can predetermine what this rate should be.

Regarding claims 27 and 28, Shalaby teaches that the suture is made from poly(glycolide-co-trimethylene carbonate polymers (¶6). The whole suture is made of this polymer.

Claims 34, 36, and 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Shalaby (US 2004/0133237).

Regarding claims 34 and 41, Shalaby teaches an absorbable medical device, such as a suture, having controlled physical properties that is irradiated with radiation from an electron beam (¶4, 6). A suture has a core and an outer surface by definition. It is the outer surface that is irradiated with the radiation because the irradiation occurs after the article has formed (¶6). These sutures are sterilized so therefore, the entire outer surface is irradiated (¶6). Shalaby also teaches that the controlled physical property can be controlled mass loss of the suture, i.e., controlled degradation of the suture through molecular weight loss. Moreover, Shalaby teaches that the it is the irradiation which changes the physical properties and the physical properties vary inversely with the radiation dose (¶5). In other words, the more radiation something receives, such as the outer surface of the suture, the less its physical property, i.e., molecular weight. Therefore, since the outer surface receives more of the radiation, it would have a lower molecular weight than the inner core of the suture. This difference in molecular weight is by definition a gradient (changes gradually). Finally, the rate of bioabsorbability, i.e., degradation, is dependent upon the molecular weight of the component. Therefore, since the outer surface has a lower molecular weight, it would have a greater rate of bioabsorbability.

Regarding claim 36, The rate of bioabsorbability (degradation) the suture (implant) is determined by the type of polymer and the amount of radiation it receives. Therefore, one can predetermine what this rate should be.

Regarding claims 39 and 40, Shalaby teaches that the suture is made from poly(glycolide-co-trimethylene carbonate polymers (¶6). The whole suture is made of this polymer.

Response to Arguments

Applicant's arguments filed July 30, 2010 have been fully considered but they are not persuasive.

Applicant's main argument surrounds the use of gamma radiation as opposed to electron beam radiation. Applicants point to Examples 1 and 3 in Shalaby for their use of gamma radiation and further conclude that all the examples in Shalaby use gamma radiation. Preceding from an alleged foundation that Shalaby only teaches the use of gamma radiation, the arguments give many reasons why the use of gamma radiation will not produce the desired, claimed results. However, applicants are reminded that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments, i.e., examples. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). MPEP 2123. Shalaby clearly teaches in paragraph [0004] that either gamma radiation or electron beam radiation is used. The fact that Shalaby uses gamma radiation in its examples does not negate the fact that electron beam radiation is clearly taught in the reference. One of ordinary skill in the art would know the properties of each type of radiation and would use the appropriate type for the appropriate type of article. Moreover, the claims only a require that the molecular weight distribution changes gradually, i.e., a gradient is produced. A gradient is simply a change in value with change in a given variable. This is a very broad term as used in the claim. A "meaningful gradient," as mentioned by the applicants on page 9 of the response, is not required. Also, the claims are for simply a substrate. There are no distinguishing characteristics, such as thickness, size, or type of article, claimed. Therefore, Shalaby teaches all the limitations of the claims as set forth and the rejections of record are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela C. Scott whose telephone number is (571) 270-3303. The examiner can normally be reached on Monday through Friday, 6:00 am to 11:00 am and 3:00 pm to 6:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1767

/A. C. S./
Examiner, Art Unit 1767
October 23, 2010